MAY - 4 2007

K062784

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: _____

1. **Submitter's Identification:**

   Name: SEJOY ELECTRONICS & INSTRUMENTS CO., LTD
   Address: 4th Floor, B2 Building, Feng-Tan-Lu Industrial Zone, West Lake District, Hangzhou, P. R. China

2. **Name of the Device:**

   Digital thermometer Model MT Series
   Including: Digital Thermometer MT-201
   Basal Digital Thermometer MT-301
   Flexible Digital Thermometer MT-402
   Instant Flexible Thermometer MT-403
   Pacifier Thermometer MT-405

3. **Predicate Device Information:**

For submitted devices MT-201 and MT-301:
* BD DIGITAL THERMOMETER
510(k) number: K945427
Applicant: BD BECTON DICKINSON VACUTAINER SYSTEMS PREANALYIC
Owner: BECTON, DICKINSON & CO.

For submitted devices MT-402 and MT-403:
* BD FLEXIBLE DIGITAL THERMOMETER
510(k) number: K902624
Applicant: BD BECTON DICKINSON VACUTAINER SYSTEMS PREANALYIC
Owner: BECTON, DICKINSON & CO.

For submitted device MT-405:
* Digital Pacifier Thermometer Model NT-01
510(k) number: K041694
Applicant: Hangzhou Hua'an Medical & Health Instrument Company Limited
Owner: Hangzhou Hua'an Medical & Health Instrument Company Limited

4. Device Description:

Digital Thermometer Model MT series (MT-201, MT-301, MT-402, MT-403 and MT-405) enable fast and reliable measurements. These thermometers provide very high clinical accuracy, and have been designed to provide maximum user-friendliness.
The basic principle of these thermometers is that a change of thermistor resistance, caused by changes of temperature, is converted to changes of frequency of R-C oscillator circuit. Therefore, temperature can be given by measuring the frequency of the oscillator.
For a given time period by applying to R-C oscillator circuit, changes of temperature will correspond to changes of pulse number.

5. Intended Use:

The devices Model MT series (MT-201, MT-301, MT-402, and MT-403) are intended to measure the human body temperature in regular mode orally, rectally or under the arm, and the devices are reusable for clinical or home use on people of all ages. The device model MT-405 is intended to measure temperature orally, and the device is reusable for clinical or home use for children less than 4 years old.

6. Comparison to Predicate Devices:

The device models MT-201, MT-301 are similar in design and intended use to the BD DIGITAL THERMOMETER, BECTON, DICKINSON & CO., differing only in physical dimensions, display resolution, battery replacement method.

The device models MT-402, MT-403 are similar in design and intended use to the BD FLEXIBLE DIGITAL THERMOMETER, BECTON, DICKINSON & CO., differing only in physical dimensions, display resolution, battery replacement method.

The device model MT-405 Pacifier Thermometer is similar in design and intended use to the Digital Pacifier Thermometer Model NT-01, Hangzhou Hua'an Medical & Health Instrument Company Limited, differing only in physical dimensions, battery replacement method.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Compliance to applicable voluntary standards includes ASTM E 1 112, as well as IEC60601-1 and IEC60601-1-2 requirements.
Guidance documents included the "FDA Guidance on the Content of Premarket Notification 510(K) Submissions for Clinical Electronic Thermometers.

8. **Discussion of Clinical Tests Performed:**

Controlled human clinical studies were conducted using the digital thermometer model MT series. Clinical data was presented which evaluated clinical bias, clinical uncertainty and clinical repeatability per the Sejoy Clinical Test Protocol outline.

9. **Conclusions:**

The digital thermometer model MT series, Model MT-201 and MT-301 have the same intended use and similar technological characteristics as the BD DIGITAL THERMOMETER.

The Model MT-402 and MT-403 have the same intended use and similar technological characteristics as the BD FLEXIBLE DIGITAL THERMOMETER.

Pacifier Thermometer MT-405 has the same intended use and similar technological characteristics as the Hua'an Medical & Health Instrument Co. LTD's Digital Pacifier Thermometer Model NT-01.

Moreover, information contained in this submission demonstrates that any differences in their characteristics do not raise any new questions of safety or effectiveness. Thus, the Digital Thermometer Model MT Series Thermometers are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sejoy Electronics & Instruments Company Limited
C/O Mr. Paul Ware
President
PW Resources, Incorporated
34 McNamara Street
Stoughton, Massachusetts 02072

MAY - 4 2007

Re: K062784
Trade/Device Name: Digital Thermometer Model MT Series
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Dated: May 4, 2007
Received: May 4, 2007

Dear Mr. Ware:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

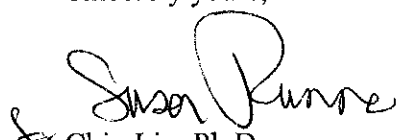
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Digital Thermometer Model MT series

Indications For Use:

The model MT series digital thermometers (MT-201, 301, 402 and 403) are intended to measure the human body temperature in regular mode orally, rectally or under the arm. The devices are reusable for clinical or home use on people of all ages.

The device model MT-405 is intended to measure oral temperature only. It is reusable for clinical or home use for children under the age of four.

Prescription Use_____ **AND/OR** **Over-The-Counter Use**__√__

(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Susan Runyon

...gn-Off)
...sion of Anesthesiology, General Hospital,
...ction Control, Dental Devices
...(k) Number: K062784